January 28, 1981

SECY-81-77

POLICY ISSUE
(Affirmation)

For: The Commissioners

From: William J. Dircks
Executive Director for Operations

Subject: FINAL AMENDMENTS TO 10 CFR PART 20 ON DISPOSAL OF CERTAIN H-3 AND C-14 WASTES

Purpose: To obtain Commission approval of a notice of final rulemaking that would (a) permit NRC licensees to dispose of liquid scintillation media and animal carcasses containing tracer levels of hydrogen-3 and carbon-14 without regard to their radioactivity, and (b) raise the limit for disposal of these radioisotopes to the sanitary sewerage systems.

Category: This paper contains a minor policy question.

Discussion: On September 19, 1980, the Commission approved proposed amendments to 10 CFR Part 20 (SECY-80-416) which were published for a 45 day public comment period which ended on November 24, 1980. Enclosure 2 is a copy of that proposed rule and a transmittal letter which was sent to 3,000 NRC materials licensees, the states and 200 interest groups and organizations.

The final rule (Enclosure 1) is the same as the proposed rule except for a clarification statement which has been added. The final rule will allow NRC licensees to dispose of liquid scintillation media and animal carcasses containing less than 0.05 microcuries of hydrogen-3 and carbon-14 per gram without regard to their radioactivity and also will allow the disposal by release into a sanitary sewerage system of up to 5 curies of hydrogen-3 and 1 curie of carbon-14 per year in addition to the

Contact:
John R. Cook, NMSS
42-24240

Edward M. Podolak, SD
44-35860

presently allowed 1 curie per year for all radionuclides. The final rule contains a statement requested by EPA which clarifies that disposal of scintillation media and animal carcasses without regard to their radioactivity will not relieve licensees from complying with other applicable regulations of federal, state and local government agencies regarding chemical and biological hazards.

The proposed rule was reviewed and endorsed by the Radiation Policy Council Task Force on Low-Level Radioactive Waste and by the NRC Advisory Committee on the Medical Uses of Isotopes.

Public Comments. The NRC received 321 comments on the proposed rule from academic and medical facilities, government agencies, professional groups, private individuals and special interest groups. Two hundred and seventy-one commenters supported the rule, 44 opposed it, and 7 commented without indicating support or opposition. The comments supporting the proposed rule come largely from those whose work would benefit from the rule and they cited the benefits of the rule to research and society. Some commenters supported the proposed rule with such statements as:

"We applaud the NRC's proposal, which is consistent with the protection of the public health, safety and welfare, to reduce the volume of low-level radioactive waste to be buried and to thereby conserve critically necessary waste burial capacity."

"The rule is a major step toward developing environmentally safe procedures to reduce low level waste volumes in the United States. NRC is to be commended for its recognition of the need for and its speed in developing the solution. All organizations that have studied low level waste problems recognize that much of the waste moving into the three disposal sites is of such low radioactivity content that it should be treated as nonradioactive in view of the high cost of disposing of hydrogen-3 and carbon-14 wastes and the large amount of disposal space being taken by this low hazard waste."

Comments opposing the rule were split mainly between those who opposed any release of radioactive material into the environment and those who expressed concern that this rule could be a first step in other rule changes leading to further release of radioactive material into the environment. None of those opposing the rule change provided new information which would cause the staff to alter its assessment of potential public exposure and environmental impacts or the benefits to be derived from the rule change. The staff did, however, make some adjustments in the final value/impact analysis (Enclosure 5) based on the public comments in order to make impacts more clear. For example, the staff performed a more rigorous assessment of collective dose as requested by the Environmental Protection Agency and others.

About one third of those supporting the rule urged the NRC to expand the scope to include other hydrogen-3 and carbon-14 waste streams or to include other radionuclides in various waste streams. Several commenters opposing the rule urged NRC to abandon it saying it might lead to other radionuclides to be considered as candidates for disposal without regard to their radioactivity. As indicated in the detailed analysis of the comments (Enclosure 6), the staff will pursue a policy of evaluating specific waste streams on a case-by-case basis as recommended by the Federal Radiation Policy Council.

One commenter questioned the need for the rule change if there were more space at waste disposal facilities. Although this question is somewhat academic because there is a severe shortage of disposal capacity available for these wastes, as indicated in the value/impact assessment and summarized later in this paper, the staff believes there are compelling economic, administrative and safety benefits to be derived from the rule change regardless of the radioactive waste disposal capacity question.

Impact of Regulations. The value/impact analysis (Enclosure 5) prepared by the staff to support the rule concludes that the rule change is the best solution to the problem of disposal of liquid scintillation media and animal carcasses containing tracer amounts of hydrogen-3 and carbon-14. It also concludes that the action is nonsubstantive and insignificant from the standpoint of environmental impact. The amount of

hydrogen-3 and carbon-14 that might be released to the environment each year as a result of the rule change pertaining to scintillation media and animal carcasses is small (28 curies and 6 curies respectively) particularly when compared to the steady state environmental inventory of 28 million curies of hydrogen-3 and 280 million curies of carbon-14. Calculations employing conservative assumptions indicate that if radiation exposure occurs as a result of the rule change the dose to exposed individuals is likely to be less than 1 millirem per year. Total health effects are estimated to be less than one health effect, even including the world population integrated over all time. This is a fraction or a percent of the annual dose and health effects attributable to natural background radiation.

The benefits to be derived from the rule change are substantial. If it is also adopted by the Agreement States, this action would save hospitals and research institutions in excess of 13 million dollars annually. It would also reduce problems associated with packaging, transport and disposal of the material in radioactive waste burial grounds and save almost one-half million cubic feet of waste disposal capacity annually.

The rule change pertaining to increasing the quantity of hydrogen-3 and carbon-14 releasable into the sanitary sewerage systems should result in impacts and benefits similar in kind to those for the scintillation media and animal carcasses rule change, although the magnitude of both the environmental impact and the benefit is expected to be less. Calculations employing conservative assumptions indicate that if radiation exposures occur as a result of the rule change the dose to individuals is likely to be much less than 1 millirem per year. The staff believes that raising the limits would benefit perhaps 20-30 NRC licensees. Although the dollar savings and savings in radioactive waste burial capacity are not known, even some savings in the cost of medical research and some savings in radioactive waste burial capacity are a direct benefit to the public.

Recommendations: The Commission:

1. Approve a notice of final rulemaking (Enclosure 1) that would (a) permit licensees to dispose of liquid scintillation media and animal carcasses containing less than 0.05 microcuries per gram of hydrogen-3 or carbon-14 without regard to their radioactivity and (b) raise the limit for disposal of these radioisotopes into the sanitary sewerage system.

2. Note:

a. The amendments would be published in the Federal Register to be effective on publication because they relieve licensees from restrictions;

b. A public announcement such as Enclosure 3 will be issued when the rule is filed with the Office of the Federal Register;

c. All affected licensees and the appropriate Congressional committees will be informed (Enclosure 4); and

d. Neither an environmental impact statement nor a negative declaration need be made in connection with this rulemaking because it is non-substantive and insignificant from the standpoint of environmental impact (Enclosure 5).

William J. Dircks
Executive Director for Operations

Enclosures:
1. Final Rule
2. Proposed Rule
3. Public Announcement
4. Congressional Letters
5. Value/Impact Analysis
6. Analysis of Comments

Commissioners' comments or consent should be provided directly to the Office of the Secretary by c.o.b. Thursday, February 12, 1981.

Commission Staff Office comments, if any, should be submitted to the Commissioners NLT February 5, 1981, with an information copy to the Office of the Secretary. If the paper is of such a nature that it requires additional time for analytical review and comment, the Commissioners and the Secretariat should be apprised of when comments may be expected.

This paper is tentatively scheduled for affirmation at an Open Meeting during the Week of February 23, 1981. Please refer to the appropriate Weekly Commission Schedule, when published, for a specific date and time.

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ENCLOSURE 1

7590-01

NUCLEAR REGULATORY COMMISSION

10 CFR Part 20

Biomedical Waste Disposal

AGENCY: Nuclear Regulatory Commission.

ACTION: Final rule.

SUMMARY: The NRC is amending its regulations to permit licensees greater leeway in disposing of liquid scintillation media and animal carcasses containing tracer levels of hydrogen-3 (tritium) or carbon-14. These rule changes will primarily affect NRC licensed hospitals and medical research institutions. Most licensees presently dispose of these items by sending them to a radioactive waste burial ground or by obtaining special authorization from NRC for incineration or onsite burial. Under the new regulations, the licensee may dispose of specified concentrations of these materials without regard to their radioactivity. The NRC is also amending its regulations to raise the annual limits for disposal of hydrogen-3 and carbon-14 by release to the sanitary sewerage systems. The rule changes will conserve waste burial capacity that is already in short supply.

EFFECTIVE DATE:

ADDRESSES: Copies of the value/impact analysis and the analysis of comments received may be examined at the Commission's Public Document Room at 1717 H Street NW., Washington D.C. Single copies of the value/impact analysis are available from John R. Cook, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555 (Telephone: 301-427-4240).

FOR FURTHER INFORMATION CONTACT: John R. Cook, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555 (Telephone: 301-427-4240).

SUPPLEMENTARY INFORMATION.

Background

Radionuclide tracers are used extensively in biomedical research and for the diagnosis of diseases in humans. One of the end products of these research and medical activities is radioactive wastes. These wastes are usually shipped to radioactive waste burial grounds although certain water soluble or dispersible wastes are released into sanitary sewerage systems. Two of the most commonly used radioisotopes in biomedical research (and to a lesser extent in medical procedures) are hydrogen-3 and carbon-14. The concentrations of these radionuclides in biomedical waste are minute, generally less than 0.05 microcuries per gram.

Liquid scintillation media and animal carcasses, both containing tracer quantities of hydrogen-3 or carbon-14, constitute the largest volume of radioactive biomedical waste.

Liquid scintillation counting has become a widespread technique for detecting radioactivity in biological samples such as blood or urine. Typically a fraction of a milliliter of the biological sample containing tracer levels of hydrogen-3 or carbon-14 is combined with 20 milliliters or less of an organic

solvent, primarily toluene, in a small vial to make a liquid scintillation medium. The vial is placed in a liquid scintillation counter, and the biological sample is assayed. The vials are used once and then collected for shipment to a radioactive waste burial ground.

Research laboratories and hospitals throughout the country presently use between 84 and 159 million vials per year, which represents between 200,000 and 400,000 gallons of liquid scintillation media. Disposal of this waste in radioactive waste burial grounds requires approximately 400,000 cubic feet of space at a cost of over $13 million per year for packing materials, transport, and disposal (this does not include the cost of licensee labor or overhead). Liquid scintillation media are approximately 43% of the total volume of radioactive waste shipped to burial grounds that is not related to industrial applications or nuclear power generation and its supporting fuel cycle.

Animals are used in research mainly for the development and testing of new drugs. Virtually every chemical compound that is considered for use as a human or veterinary drug is first tagged with a hydrogen-3 or carbon-14 tracer and injected into research animals to study how the chemical compound behaves. These research animals include mice, rats, dogs, monkeys, swine, and sheep. The animal carcasses containing trace quantities of hydrogen-3 and carbon-14 are usually shipped to radioactive waste burial grounds. Animal carcasses annually require about 80 thousand cubic feet of burial space at a cost of almost $3 million per year. Animal carcasses are approximately 9% of the total volume of radioactive waste shipped to burial grounds that is not related to industrial applications or nuclear power generation and its supporting fuel cycle.

There are other hydrogen-3 and carbon-14 waste streams in the research laboratory that do not result in liquid scintillation vials and animal carcasses; for example, the solutions and attendant material used to prepare the research samples. These materials also contain tracer levels of hydrogen-3 and carbon-14.

Under present NRC regulations, hydrogen-3 and carbon-14 wastes that are readily soluble or dispersible in water can be disposed of by release to the sanitary sewerage systems. The annual limit for release to the sanitary sewerage systems is found in 10 CFR §20.303 and is limited to a total of 1 curie for all radionuclides per year for each licensee. This proposed rule would raise the limit for hydrogen-3 to 5 curies per year and the limit for carbon-14 to 1 curie per year. This change would result in a negligible addition to the level of these radioisotopes already present in the natural environment.

There are alternatives for disposal of liquid scintillation media and animal carcasses containing hydrogen-3 and carbon-14 other than consignment to a radioactive waste burial ground. Liquid scintillation media can be evaporated, distilled, burned, or buried on a licensee's site if an appropriate location is available. Animal carcasses can be incinerated in a pathogen incinerator. Currently, none of these alternatives to radioactive waste burial are readily available. Generally, liquid scintillation media and animal carcasses with <u>any</u> added hydrogen-3 or carbon-14 are being handled as radioactive waste and consigned to a radioactive waste burial ground under NRC's regulations (10 CFR §§30.41 and 20.301) and similar Agreement State regulations.

The state agencies that control the existing radioactive waste burial grounds do not want to accept liquid scintillation media or animal carcasses. Liquid scintillation media are flammable and are suspected of leaching radioactive chemicals out of the burial trenches. Also, some of the shipping containers arrive at the burial grounds leaking. Liquid scintillation media are chemically toxic and are suspected of being carcinogenic and thus pose a waste hazard unrelated to their radioactive character. Animal carcasses decompose and can be a pathogen hazard. Sometimes the animal carcasses will cause their containers to burst during shipment. The voids formed in the burial trenches by the decaying animal carcasses are also believed to contribute to migration of chemicals by increasing rain water percolation in the trenches.

The three operating commercial radioactive waste burial grounds in the U.S. are located in Barnwell, South Carolina; Beatty, Nevada; and Richland, Washington. The Richland, Washington and Beatty, Nevada sites accept both liquid scintillation media and animal carcasses. However, after December 1984, the Richland, Washington site will not accept liquid scintillation media. The Barnwell, South Carolina site does not accept liquid scintillation media but does accept animal carcasses. At all three sites, the state regulatory bodies are attempting to reduce the volume of incoming waste to prolong site use.

During a temporary state-imposed embargo in mid-1979, some hospitals and research institutions across the country apparently came within days of curtailing operations involving liquid scintillation counting and animal research before the radioactive waste burial grounds in Richland, Washington and Beatty, Nevada resumed accepting liquid scintillation vials and animal carcasses.

The Rule

This final rulemaking will allow NRC licensees to dispose of liquid scintillation media and animal carcasses containing less than 0.05 microcuries of hydrogen-3 or carbon-14 per gram without regard to their radioactivity. This regulation will not relieve licensees from complying with other applicable regulations of federal, state, and local government agencies regarding the disposal of non-radioactive materials. Scintillation media are toxic and flammable, and animal carcasses are sometimes pathogenic. These characteristics, which are a more important public health problem than their radioactivity, may require them to be disposed of under applicable federal, state, and local laws governing chemical and biological hazards. This rulemaking will also allow licensees to dispose by release to sanitary sewerage systems of up to 5 curies of hydrogen-3 and 1 curie of carbon-14 per year, in addition to the presently allowed 1 curie per year for all radionuclides. Neither the rulemaking allowing disposal of liquid scintillation media and animal carcasses without regard to their radioactivity nor that raising the limit for disposal of hydrogen-3 and carbon-14 to sanitary sewerage, authorizes disposal of liquid scintillation media (e.g., toluene) into the sanitary sewerage systems.

Because the amount of hydrogen-3 and carbon-14 that could be released to the environment as a result of this rulemaking is very small, and because calculations employing conservative assumptions indicate the dose to any exposed individual is likely to be much less than 1 millirem per year, the Commission believes that the rulemaking will have little adverse impact from a radiological health standpoint.

The rule will essentially remove any NRC restrictions on the disposal of liquid scintillation media and animal carcasses. It will no longer be necessary for NRC licensees to ship these materials, which could pose a chemical and biological hazard, up to thousands of miles across the country for disposal in a radioactive waste burial ground. NRC Agreement States could make similar amendments to their regulations in order to extend the benefit of this action to their licensees.

The analysis prepared by the NRC staff to support the rule concludes that this rule change is the best solution to the problem of disposal of liquid scintillation media and animal carcasses containing tracer amounts of hydrogen-3 and carbon-14. The value/impact analysis indicates that the action is non-substantive and insignificant from the standpoint of environmental impact. If also adopted by the Agreement States, this action would save hospitals and research institutions in excess of $13 million annually ($16 million for the cost of packaging materials, transportation, and disposal, minus the $3 million estimated for non-radioactive waste disposal). Also, it will save almost one-half million cubic feet of radioactive waste burial capacity annually, or half of that used for radioactive waste not related to industrial applications or nuclear power generation and its supporting fuel cycle.

In summary, the proposed amendments concerning the disposal of tracer levels of hydrogen-3 and carbon-14 in liquid scintillation media and animal carcasses are appropriate because: (a) the amendments will not pose an unreasonable risk to the common defense and security and to the health and safety of the public; (b) disposal of these wastes in radioactive waste burial grounds

is expensive and without benefit commensurate with the expense, (c) the flammability of liquid scintillation media (organic solvents) and the decomposition of animal carcasses cause a significant problem in transporting these wastes to burial grounds, and (d) these wastes consume a significant portion of radioactive waste burial capacity which is in short supply.

Similarly, the amendment raising the limit for sanitary sewerage disposal of hydrogen-3 and carbon-14 is appropriate because it will not pose an unreasonable risk to the public. In addition, the shipment of this waste to radioactive waste burial grounds is costly and consumes valuable burial space that could be made available for more hazardous radioactive waste.

The Comments

This rule was published as a proposed rule in the Federal Register of October 8, 1980 (45 FR 67018). The final rule is essentially the same as the proposed rule except for minor editorial changes and an additional statement regarding the non-radioactive hazardous and toxic properties of the wastes. This additional statement was included at the request of the Environmental Protection Agency and is discussed below under the heading Fate of Wastes. The Federal Register notice on the proposed rule contained essentially the same background information provided above, and invited public comments for a 45 day period ending November 24, 1980.

NRC received 321 comments on the proposed rule from academic institutions, medical facilities, state governments, professional groups, private individuals and special interest groups. Two hundred seventy one commenters supported the rule, 44 opposed it and 7 commented without indicating support or opposition. The comments supporting the rule came primarily from institutions, professional groups and individuals whose work would benefit from the rule and they cited those benefits both to their research and to society. The comments opposing the rule were split between individuals who were opposed to any release of radioactive material into the environment and individuals or special interest groups who were concerned about where this rule would lead, i.e., to a policy of dispersal of radioactive material as opposed to containment.

The comments addressed the following aspects of the proposed rule.

Need

Most of the 271 commenters who supported the rule stated their reasons. Their reasons are basically the same as those stated in the preamble to this rulemaking. The estimates of annual savings offered by the commenters if the proposed regulations went into effect ranged from $2,000-$250,000, depending on the size of the institution's biomedical program. Some of the organizations that supported the rule were the National Institutes of Health, the American Medical Association, the American College of Nuclear Physicians, the American College of Radiology, the American Hospital Association, the Joint Commission on Accreditation of Hospitals, the Society of Nuclear Medicine, the Endocrine Society, the American Council on Education, Scientists for Public Safety and the Intersociety Council for Biology and Medicine.

A few of the opposing comments questioned the need for the rulemaking. One of these commenters asked, "If there were no space problems, would the question of changing the regulations ever have arisen?"

The answer to this question is yes, the regulations need changing even without the problem of space in the burial grounds because present regulations impose an economic and administrative burden on licensees that is not justified. As one commenter who favored the proposed rule observed:

> "...My own experience is that the strict regulations now in effect have resulted in the holding of hundreds of dead carcasses until money becomes available for proper packaging of these materials for disposal. The result has been a significant reduction in research and a reluctance to undertake projects which involve low levels of radioactivity in animals. Thus, my experience indicates that present restrictions have innibited research..."

There are additional reasons for the rule changes regarding safety at the burial grounds, transportation to the burial grounds and safety in the laboratory. The problems in shipping these wastes to the burial grounds and the problems that these wastes cause in the burial trenches are discussed above under Background. Regarding safety in the laboratory, one commenter favoring the regulation observed:

> "I believe the effort expended in meeting previous regulations has been more damaging to the health of my laboratory personnel than the small amount of radiation, i.e., difficulties of lung and skin exposure to toluene-based fluids (despite the use of hoods, gloves, etc.). I hope these hazards will decrease with these rules."

Scope

While one-third of the commenters supporting the rule urged NRC to expand the scope of the rule to include other hydrogen-3 and carbon-14 waste streams or to include other radionuclides in various waste streams, several of the commenters opposing the rule urged NRC to abandon the rule because it might lead to other rulemakings identifying further waste streams or radionuclides as candidates for disposal without regard to their radioactivity. These latter commenters most often cited the need for a comprehensive environmental analysis covering all possible radionuclides and all possible waste streams as their reason for opposing this present rulemaking.

The Commission is aware of the merit of having one comprehensive rulemaking to include many or perhaps all of the possible radionuclides and waste streams. This type of comprehensive rulemaking and its associated generic environmental analysis of all of the benefits and risks is theoretically an optimum approach, but as a practical matter it is an unworkable approach. The practical approach is to examine the specific waste streams which contribute a large volume to the burial grounds as candidates for alternative regulatory approaches. The U.S. Radiation Policy Council at their September 25, 1980 public meeting discussed both the generic approach and the specific waste streams approach. At that meeting the Council:

> "Adopted a Federal policy acknowledging that there are concentrations of specific radionuclides in specific waste streams which pose such small risks that control for radiation protection purposes is not necessary. In accordance with this policy requested that the NRC present to the (Council's) Working Group by November 18 an interim plan for identification and analysis of specific waste streams beginning with the C-14 and H-3 (tritium) medical waste streams for which early action is appropriate and develop a proposed regulatory framework for this activity."

Single copies of that interim plan, called for by the Council, are available from John R. Cook at the above address.

Fate of Wastes

Several commenters, both for and against the proposed rule, expressed concern about the fate of these biomedical wastes if the NRC allowed disposal without regard to their radioactivity. Most of these commenters were concerned that the liquid scintillation medium toluene, which is flammable and toxic, would be poured down the drain and into the sanitary sewerage systems. The Environmental Protection Agency (EPA), while supporting NRC's amendment covering liquid scintillation media and animal carcasses, recommended that the regulation itself include a clarifying statement that disposal of scintillation media and animal carcasses without regard to their radioactivity will not relieve licensees from complying with other applicable regulations of federal, state and local government agencies regarding chemical and biological hazards. This recommendation was echoed by two other commenters. Also, a group of sanitation workers expressed concern that they might face an increased occupational hazard from the radioactive wastes, which they believed might concentrate in certain sewerage system components.

The preambles to both the proposed rule and this final rule include a statement similar to that recommended by EPA and others. However, the Commission agrees with EPA and those commenters who would like to see such a clarifying statement in the regulation itself regarding the non-radioactive hazards of liquid scintillation media and animal carcasses. Therefore, a statement has been added to the final rule at 10 CFR §20.306(d) as follows:

> "(d) Nothing in this section relieves the licensee from complying with other applicable federal, state, and local regulations governing any other toxic or hazardous property of these materials."

Finally, regarding the question of a radiation hazard to sanitation workers from deposition in sewerage system components, because the hydrogen-3 and carbon-14 behave chemically the same as non-radioactive hydrogen and carbon, there is no reason to expect significant deposition or accumulation in sewerage system components. Further, hydrogen-3 and carbon-14 emit weak beta radiations, which are completely shielded by piping, conduit, ground, water, etc.

Concentration Limit

A few commenters questioned the concentration limit in the proposed rule which was set at 0.05 microcuries or less of hydrogen-3 or carbon-14, per gram of liquid scintillation medium or animal tissue. Some commenters simply asked about the basis for the 0.05 microcuries per gram value. One commenter said the concentration limit should be raised to 0.1-0.2 microcuries per gram. Another commenter said that the concentration limit should be lowered to 0.02 or 0.025 microcuries per gram.

The commenter who suggested raising the concentration limit said that this could be done on the basis of the analysis of risks due to releases at these levels. The commenter who suggested lowering the proposed concentration limit offered an analysis which shows that 0.05 microcuries per gram is too high an activity for liquid scintillation counting and that 0.02 microcuries per gram will cover most applications of liquid scintillation counting. This latter commenter pointed out that the "as low as is reasonably achievable" (ALARA) concept of radiation protection dictates going to the lower concentration limit. This same commenter argued for an overall release limit for each licensee based on his analysis which assumes that all of the 200,000-400,000 gallons of liquid scintillation media are released at the maximum 0.05 microcuries per gram level.

The 0.05 microcuries per gram concentration limit was recommended to the Commission by its expert consultants as a level that would cover most biomedical research involving tracer use in animals. The Commission adopted the same level for liquid scintillation media as an administrative simplification, recognizing that the 0.05 microcuries per gram level will be higher than that normally encountered in liquid scintillation work. If the limit were set much closer to the concentrations actually used, licensees would be required to perform more exacting calculations and analytical steps to demonstrate compliance with the rule. This adds to the cost of administration for both the licensees and NRC. Setting the concentration limit at 0.05 microcuries per gram for both animal carcasses and liquid scintillation media does not violate the ALARA principle because the concentrations actually used are controlled by the sensitivity of the counting equipment and the cost of hydrogen-3 and carbon-14 labelled compounds which typically are quite expensive.

The Commission derived its estimates of the potential quantities of hydrogen-3 and carbon-14 released to the environment as a result of this rule-making from actual production and use data. It would be erroneous to assume that all of the liquid scintillation media would be released at the maximum 0.05 microcuries per gram concentration. This assumption leads to release estimates that exceed the total produced for such uses.

Basically, the value/impact analysis does not indicate the need for a maximum release limit for each licensee. The Commission does not believe that setting the concentration limit higher than that actually used in practice will result in unnecessary (non-ALARA) releases to the environment. The Commission does believe that these higher limits will reduce the cost of administration of these regulations.

Value/Impact Analysis

Several commenters both for and against the proposed rule commented on the preliminary value/impact analysis. A few commenters suggested that the final value/impact analysis consider the impact of multiple users on a common sewerage system disposing of hydrogen-3 and carbon-14 under the new limits. Also, the Environmental Protection Agency recommended lower dilution factors for this part of the analysis. The Commission agrees with these comments and the final value/impact analysis addresses the impact of multiple users and employs adjusted dilution factors. The conclusion of the analysis, however, has not changed, i.e., the amendment raising the limit for sanitary sewerage disposal of hydrogen-3 and carbon-14 is appropriate because it will not pose an unreasonable risk to the public.

The Environmental Protection Agency and at least one other commenter observed that the information presented in the preliminary value/impact analysis was not sufficient to support the need to raise the limits for hydrogen-3 and carbon-14 which can be discharged to sanitary sewers. The EPA also states that the increased health risk from the release of hydrogen-3 and carbon-14 in the quantities now in use appears to be very low.

The Commission believes that raising the limits for release of hydrogen-3 and carbon-14 to the sanitary sewerage systems will benefit perhaps 20-30 NRC licensees. The dollar savings in radioactive waste burial capacity are not known; however, even some savings in the cost of medical research and some savings in radioactive waste burial capacity are a direct benefit to the public and should not be foregone because they are difficult to quantify.

Finally, the Environmental Protection Agency noted that the preliminary value/impact analysis gave estimates of the individual doses which might result from the proposed changes; however, they suggested that the final value/impact analysis include an assessment of the collective dose commitment. The preliminary value/impact analysis included a brief treatment of the collective dose commitment. The final value/impact analysis includes a more rigorous treatment of this question. However, the conclusion of the final value/impact analysis has not changed. Basically, the value/impact analysis concludes this rulemaking is non-substantive and insignificant from the standpoint of environmental impact.

Clarifications

Several commenters requested clarification on the boundaries of the rule change. Does the term liquid scintillation media include the vials containing the media? Does the term animal tissue include organs or fluids which may have been removed from the carcasses for analysis?

The regulation in 10 CFR §20.306(a) applies to the disposal of liquid scintillation media of 0.05 microcuries or less of hydrogen-3 or carbon-14 per gram of medium. Licensees may dispose of liquid scintillation media containing this concentration of hydrogen-3 or carbon-14 without regard to its radioactivity. Scintillation vials themselves are not radioactive. Rather, it is the scintillation media remaining in the vials that contains the radioactivity. The rule covers that material. Therefore, it would be permissible to dispose of the used vials along with the media.

Similarly, the regulation in 10 CFR §20.306(b) applies to the disposal of animal tissue of 0.05 microcuries or less of hydrogen-3 or carbon-14 per gram of tissue averaged over the weight of the entire animal, whether the tissue (or organ) is ultimately removed from the carcass or not. However, the regulation does not apply to either the radioactive chemicals before they are administered to the animals or to the animal feces or urine or contaminated bedding.

Finally, some commenters asked if the rule change would permit incineration of the scintillation media and animal carcasses without obtaining permission from NRC via a license amendment. The answer is, yes, liquid scintillation media and animal carcasses may be incinerated without a license amendment to the extent permitted by applicable non-radioactive waste disposal regulations.

Authority

This rule is being made effective on the date of publication in the Federal Register because it relieves licensees from restrictions.

Under the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974, as amended, and Sections 552 and 553 of Title 5 of the United States Code, the following amendments to Title 10, Chapter I, Code of Federal Regulations, Part 20, are published as a document subject to codification.

Part 20 -- STANDARDS FOR PROTECTION AGAINST RADIATION

1. In §20.301, paragraph (c) is revised to read as follows:*

§20.301 General requirement.

* * * * *

(c) As provided in §20.303, applicable to the disposal of licensed material by release into sanitary sewerage systems, or in §20.306 for disposal of specific wastes, or in §20.106 (Radioactivity in effluents to unrestricted areas).

* Additions to the present rule are underlined.

2. In §20.303, paragraph (d) is revised to read as follows:

§20.303 Disposal by release into sanitary sewerage systems.

* * * * *

(d) The gross quantity of licensed and other radioactive material, excluding hydrogen-3 and carbon-14, released into the sewerage system by the licensee does not exceed one curie per year. The quantities of hydrogen-3 and carbon-14 released into the sanitary sewerage system may not exceed 5 curies per year for hydrogen-3 and 1 curie per year for carbon-14. Excreta from individuals undergoing medical diagnosis or therapy with radioactive material shall be exempt from any limitations contained in this section.

3. §20.305 is revised to read as follows:

§20.305 Treatment or disposal by incineration.

No licensee shall treat or dispose of licensed material by incineration except for materials listed under §20.306 or as specifically approved by the Commission pursuant to §§20.106 (b) and 20.302.

4. A new §20.306 is added to read as follows:

§20.306 Disposal of specific wastes

Any licensee may dispose of the following licensed material without regard to its radioactivity:

(a) 0.05 microcuries or less of hydrogen-3 or carbon-14, per gram of medium, used for liquid scintillation counting; and

(b) 0.05 microcuries or less of hydrogen-3 or carbon-14, per gram of animal tissue averaged over the weight of the entire animal; provided however, tissue may not be disposed of under this section in a manner that would permit its use either as food for humans or as animal feed.

(c) Nothing in this section, however, relieves the licensee of maintaining records showing the receipt, transfer and disposal of such byproduct material as specified in §30.51 of Part 30 of this chapter; and

(d) Nothing in this section relieves the licensee from complying with other applicable federal, state and local regulations governing any other toxic or hazardous property of these materials.

* * * * *

[Sec. 161b, Pub. L. 83-703, 68 Stat. 948 (42 U.S.C. 2201), Sec. 201, Pub. L. 93-438, 88 Stat. 1242 (42 U.S.C. 5841)]

Dated at Washington, D.C., this _____ day of _____ 1981.

FOR THE NUCLEAR REGULATORY COMMISSION

Samuel J. Chilk
Secretary of the Commission

ENCLOSURE 2

UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D. C. 20555

October 10, 1980

TO ALL MATERIAL LICENSEES AND ADDRESSEES

The Nuclear Regulatory Commission is considering amending its regulations to permit licensees greater leeway in disposing of liquid scintillation media and animal carcasses containing tracer levels of hydrogen-3 (tritium) or carbon-14. Most licensees presently dispose of these items by sending them to a radioactive waste burial ground or by obtaining special authorization fror NRC for incineration or onsite burial. A copy of the proposed regulations is enclosed.

Under the proposed regulations, the licensee may dispose of specified concentrations of these materials without regard to their radioactivity. The NRC is also considering amending its regulations to raise the annual limits for disposal of hydrogen-3 and carbon-14 by release to the sanitary sewerage system. The proposed rule changes would conserve waste burial capacity that is already in short supply.

Interested persons are invited to submit written comments and suggestions for consideration on the proposed amendments to the Secretary of the Commission, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, Attention: Docketing and Service Branch. Please refer to Docket No. PR 20 (45 FR 67018). Comments received after November 24, 1980, will be considered if it is practical to do so, but assurance of consideration cannot be given except as to comments filed on or before that date.

for Richard E. Cunningham, Director
Division of Fuel Cycle and
Material Safety

Enclosure: Federal Register Notice

DS UPPS0210T0321

ENCLOSURE 2

NUCLEAR REGULATORY COMMISSION

10 CFR Part 20

Standards for Protection Against Radiation

AGENCY: Nuclear Regulatory Commission.

ACTION: Proposed rule.

SUMMARY: The NRC is considering amending its regulations to permit licensees greater leeway in disposing of liquid scintillation media and animal carcasses containing tracer levels of hydrogen-3 (tritium) or carbon-14. Most licensees presently dispose of these items by sending them to a radioactive waste burial ground or by obtaining special authorization from NCR for incineration or on site burial. Under the proposed regulations, the licensee may dispose of specified concentrations of these materials without regard to their radioactivity. The NRC is also considering amending its regulations to raise the annual limits for disposal of hydrogen-3 and carbon-14 by release to the sanitary sewerage system. The proposed rule changes would conserve waste burial capacity that is already in short supply.

DATE: Comment period expires November 24, 1980.

Note.—Comments received after the expiration date will be considered if it is practical to do so, but assurance of consideration cannot be given except as to comments filed on or before that date.

ADDRESSES: Interested persons are invited to submit written comments and suggestions for consideration on the proposed amendments to the Secretary of the Commission, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, attention: Docketing and Service Branch. Copies of the preliminary value/impact analysis and of comments received may be examined at the Commission's Public Document Room at 1717 H Street NW., Washington, D. C. Single copies of the preliminary value/impact analysis are available from John R. Cook at the phone number and address listed below.

FOR FURTHER INFORMATION CONTACT: John R. Cook, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555 (Telephone: 301–427–4240).

SUPPLEMENTARY INFORMATION: Radionuclide tracers are used extensively in biomedical research and for the diagnosis of diseases in humans. One of the end products of these research and medical activities is radioactive wastes. These wastes are usually shipped to radioactive waste burial grounds although certain water soluble or dispersible wastes are released into sanitary sewerage systems. Two of the most commonly used radioisotopes in biomedical research (and to a lesser extent in medical procedures) are hydrogen-3 and carbon-14. The concentrations of these radionuclides in biomedical waste are minute, generally less than 0.05 microcuries per gram.

Liquid scintillation media and animal carcasses, both containing tracer quantities of hydrogen-3 or carbon-14, constitute the largest volume of radioactive biomedical waste.

Liquid scintillation counting has become a widespread technique for detecting radioactivity in biological samples such as blood or urine. Typically, a fraction of a milliliter of the biological sample containing tracer levels of hydrogen-3 or carbon-14 is combined with 20 milliliters or less of an organic solvent, primarily toluene, in a small vial to make a liquid scintillation medium. The vial is placed in a liquid scintillation counter, and the biological sample is assayed. The vials are used once and then collected and shipped to a radioactive waste burial ground.

Research laboratories and hospitals throughout the country presently use between 84 and 159 million vials per year, which represents between 200,000 and 400,000 gallons of liquid scintillation media. Disposal of this waste in radioactive waste burial grounds requires approximately 400,000 cubic feet of space at a cost of over $13 million per year for packing materials, transport, and disposal (this does not include the cost of licensee labor or overhead). Liquid scintillation media are approximately 43% of the total volume of radioactive waste shipped to burial grounds that is not related to nuclear power generation and its supporting fuel cycle.

Animals are used in research mainly for the development and testing of new drugs. Virtually every chemical compound that is considered for use as a human or veterinary drug is first tagged with a hydrogen-3 or carbon-14 tracer and injected into research animals to study how the chemical compound behaves. These research animals include mice, rats, dogs, monkeys, swine, and sheep. The animal carcasses containing trace quantities of hydrogen-3 and carbon-14 are usually shipped to radioactive waste burial grounds. Animal carcasses annually require about 30 thousand cubic feet of burial space at a cost of almost $3 million per year. Animal carcasses are approximately 9% of the total volume of radioactive waste shipped to burial grounds that is not related to nuclear power generation and its supporting fuel cycle.

There are other hydrogen-3 and carbon-14 waste streams in the research laboratory that do not result in liquid scintillation vials and animal carcasses; for example, the solutions and attendant material used to prepare the research samples. These materials also contain tracer levels of hydrogen-3 and carbon-14.

Under present NRC regulations, hydrogen-3 and carbon-14 wastes that are readily soluble or dispersible in water can be disposed of by release to the sanitary sewerage system. The annual limit for release to the sanitary sewerage system is found in 10 CFR 20.303 and is limited to a total of 1 curie of all radionuclides per year for each licensee. This proposed rule would raise the limit for hydrogen-3 to 5 curies per year and the limit for carbon-14 to 1 curie per year. This change would result in a negligible addition to the level of these radioisotopes already present in the natural environment.

There are alternatives for disposal of liquid scintillation media and animal carcasses containing hydrogen-3 and carbon-14 other than consignment to a radioactive waste burial ground. Liquid scintillation media can be evaporated, distilled, burned, or buried on a licensee's site if an appropriate location is available. Animal carcasses can be incinerated in a pathogen incinerator. Currently, none of these alternatives to radioactive waste burial are readily available. Generally, liquid scintillation media and animal carcasses with *any* added hydrogen-3 or carbon-14 are being handled as radioactive waste and consigned to a radioactive waste burial ground under NRC's regulations (§§ 30.41 and 20.301) and similar Agreement State regulations.

The state agencies that control the existing radioactive waste burial grounds do not want to accept liquid scintillation media or animal carcasses. Liquid scintillation media are flammable and are suspected of leaching radioactive chemicals out of the burial trenches. Also, some of the shipping containers arrive at the burial grounds leaking. Liquid scintillation media are chemically toxic and are suspected of being carcinogenic and thus pose a waste hazard unrelated to their radioactive character. Animal carcasses decompose and can be a pathogen hazard. Sometimes the animal carcasses will cause their containers to burst during shipment. The voids formed in the burial trenches by the decaying

animal carcasses are also believed to contribute to migration of chemicals by increasing rain water percolation in the trenches.

The three radioactive waste burial grounds in the U.S. are located in Barnwell, South Carolina; Beatty, Nevada; and Richland, Washington. The Richland, Washington and Beatty, Nevada sites accept both liquid scintillation media and animal carcasses. The Barnwell, South Carolina site does not accept liquid scintillation media but does accept animal carcasses. At all three sites, the state regulatory bodies are attempting to reduce the volume of incoming waste to prolong site use.

During a temporary state-imposed embargo in mid-1979, some hospitals and research institutions across the country apparently came within days of curtailing operations involving liquid scintillation counting and animal research before the radioactive waste burial grounds in Richland, Washington and Beatty, Nevada resumed accepting liquid scintillation vials and animal carcasses.

The Rule

This rulemaking would allow NRC licensees to dispose of liquid scintillation media and animal carcasses containing less than 0.05 microcuries of hydrogen-3 or carbon-14 per gram without regard to their radioactivity.

This regulation would not relieve licensees from complying with other applicable regulations of Federal, state, and local government agencies regarding the disposal of non-radioactive materials. Scintillation media are toxic and flammable, and animal carcasses are sometimes pathogenic. These characteristics, which are a more important public health problem than their radioactivity, may require them to be disposed of under applicable Federal, state, and local laws governing chemical and biological hazards. This rulemaking would also allow the disposal by release to a sanitary sewerage system of up to 5 curies of hydrogen-3 and 1 curie of carbon-14 per year, in addition to the presently allowed 1 curie per year for all radionuclides. Neither the rulemaking allowing disposal of liquid scintillation media and animal carcasses without regard to their radioactivity nor that raising the limit for disposal of hydrogen-3 and carbon-14 to sanitary sewerage authorized disposal of liquids scintillation media (e.g., toluene) into the sanitary sewerage system.

Because the amount of hydrogen-3 and carbon-14 that could be released to the environment as a result of this rulemaking is very small, and because calculations employing conservative assumptions indicate the dose to any exposed individual is likely to be much less than 1 millirem per year, the Commission believes that the rulemaking would have little adverse impact from a radiological health standpoint.

The rule would essentially remove any NRC restrictions on the disposal of liquid scintillation media and animal carcasses. It would no longer be necessary for NRC licensees to ship these materials, which could pose a chemical and biological hazard, up to thousands of miles across the country for disposal in a radioactive waste burial ground. NRC Agreement States could make similar amendments to their regulations in order to extend the benefit of this action to their licensees.

The preliminary value/impact analysis prepared by the NRC staff to support the proposed rule concludes that this rule change is the best solution to the problem of disposal of liquid scintillation media and animal carcasses containing tracer amounts of hydrogen-3 and carbon-14. The preliminary value/impact analysis indicated that the action is non-substantial and insignificant from the standpoint of environmental impact. If also adopted by the Agreement States, this action would save hospitals and research institutions in excess of $13 million annually ($16 million for the cost of packaging materials, transportation, and disposal, minus the $3 million estimated for non-radioactive waste disposal). Also, it would save almost one-half million cubic feet of radioactive waste burial capacity annually, or half of that used for radioactive waste not related to nuclear power generation and its supporting fuel cycle.

In summary, the proposed amendments concerning the disposal of tracer levels of hydrogen-3 and carbon-14 in liquid scintillation media and animal carcasses would be appropriate because: (a) the proposed amendments would not pose an unreasonable risk to the common defense and security and to the health and safety of the public; (b) disposal of these wastes in radioactive waste burial grounds is expensive and without benefit commensurate with the expense; (c) the flammability of liquid scintillation media (organic solvents) and the decomposition of animal carcasses cause a significant problem in transporting these wastes to burial grounds; and (d) these wastes consume a significant portion of radioactive waste burial capabity which is in short supply.

Similarly, the amendment raising the limit for sanitary sewerage disposal of hydrogen-3 and carbon-14 is appropriate because it would not pose an unreasonable risk to the public. In addition, the shipment of this waste to radioactive waste burial grounds is costly and consumes valuable burial space that could be made available for more hazardous radioactive waste.

The Commission has decided that a 45 day comment period for this rulemaking is appropriate because the potential radiological impacts are small and there is a shortage of available burial ground capacity.

Under the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974, as amended, and section 553 of Title 5 of the United States Code, notice is hereby given that adoption of the following amendments to 10 CFR Part 20 is contemplated.

1. In § 20.301, paragraph (c) is revised to read as follows:

§ 20.301 General requirement.

* * * * *

(c) As provided in § 20.303 or § 20.304, applicable respectively to the disposal of licensed material by release into sanitary sewerage systems or burial in soil, or in § 20.306 for disposal of specific wastes, or in § 20.106 (Radioactivity in effluents to unrestricted areas).

2. In § 20.303, paragraph (d) is revised to read as follows:

§ 20.303 Disposal by release into sanitary sewerage systems.

* * * * *

(d) The gross quantity of licensed and other radioactive material, excluding hydrogen-3 and carbon-14, released into the sewerage system by the licensee does not exceed one curie per year. The quantities of hydrogen-3 and carbon-14 released into the sanitary sewerage system may not exceed 5 curies per year for hydrogen-3 and 1 curie per year for carbon-14. Excreta from individuals undergoing medical diagnosis or therapy with radioactive material shall be exempt from any limitations contained in this section.

3. § 20.305 is revised to read as follows:

§ 20.305 Treatment or disposal by incineration.

No licensee shall treat or dispose of licensed material by incineration except for materials listed under § 20.306 or as specifically approved by the Commission pursuant to §§ 20.106(b) and 20.302.

4. A new § 20.306 is added to read as follows:

§ 20.306 Disposal of specific wastes.

(a) Any licensee may dispose of the following licensed material without regard to its radioactivity:

(1) 0.05 microcuries or less of hydrogen-3 or carbon-14, per gram of medium, used for liquid scintillation counting; and

(2) 0.05 microcuries or less of hydrogen-3 or carbon-14, per gram of animal tissue averaged over the weight of the entire animal; provided however, tissue may not be disposed of under this section in a manner that would permit its use either as food for humans or as animal feed.

(b) Nothing in this section, however, relieves the licensee of maintaining records showing the receipt, transfer, and disposal of such byproduct material as specified in § 30.51 of this chapter.

(Sec. 81, 161b, Pub. L. 83-703, 68 Stat. 935, 948, as amended (42 U.S.C. 2111, 2201); Sec. 201, Pub. L. 93-438, 88 Stat. 1242 (42 U.S.C 5841))

Dated at Washington, DC, this 2d day of October, 1980.

For the Nuclear Regulatory Commission.

Samuel J. Chilk,

Secretary of the Commission.

[FR Doc. 80-31316 Filed 10-7-80; 8:45 am]

BILLING CODE 7590-01-M

ENCLOSURE 3

NRC CHANGES REGULATIONS ON DISPOSAL OF RADIOACTIVE WASTES RESULTING FROM MEDICAL RESEARCH

The Nuclear Regulatory Commission is changing its regulations to eliminate the requirement that licensed biomedical research laboratories and hospitals send animal carcasses and vials containing tracer amounts of certain radioactive materials to radioactive waste burial grounds. Under the amended regulations, licensees will be able to dispose of these materials without regard to their radioactivity.

The licensed materials covered by the changes are:

1) 0.05 microcuries or less of hydrogen-3 or carbon-14, per gram of liquid scintillation media, and

2) 0.05 microcuries or less of hydrogen-3 or carbon-14, per gram of animal tissue averaged over the weight of the entire animal.

Tracer amounts of hydrogen-3 and carbon-14 are added to chemical compounds or experimental drugs to study the drugs' behavior in research animals. After the drug containing radioactive material is administered to an animal, a sample from the animal's urine, blood or body tissue is combined with an organic solvent--such as toluene--in a small vial to make a "liquid scintillation medium." The vial is placed in a "liquid scintillation counter," which measures the amount of radioactivity in the sample. The radioactivity amount can be used to derive the needed information on the behavior of the drug. The vials are used once and then are ready for disposal.

ENCLOSURE 3

Most NRC licensees currently dispose of these vials and the animal carcasses containing radioactive materials by sending them to a radioactive waste burial ground. The vials and carcasses together constitute the largest volume of radioactive medical waste.

The amount of hydrogen-3 and carbon-14 that could be released to the environment as a result of the amendments to permit burial of these items without regard to their radioactivity is very small. Calculations indicate that the dose to any exposed person is likely to be much less than 1 millirem per year (as compared to a dose of about 3 millirems to persons flying a single round trip coast-to-coast on airliners). The Commission therefore believes that the changes to the regulations will have little adverse impact on the environment from a radiological health standpoint.

On the benefit side, the rule changes will permit the conservation of radioactive waste burial capacity that is already in short supply and will alleviate the significant problems involved in transporting to the waste burial grounds the liquid scintillation media (containing flammable toluene) and decomposing animal carcasses.

Other portions of the amendments will raise the limit for the amount of hydrogen-3 and carbon-14 that may be released to sewerage systems. Under present NRC regulations, a licensee may release a total of 1 curie per year of all radioactive materials in this manner. The revised regulations raising the limit for hydrogen-3 to 5 curies per year and for carbon-14 to 1 curie per year will result in a negligible addition to the amount of radioactivity already present in the natural environment.

The amendments, which are to Part 20 of the Commission's regulations, will be effective on the date of publication in the Federal Register (_____ _____). They were published in the Federal Register in proposed form on October 8, 1980, for public comment. No significant changes have been made as a result of the comments received.

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ENCLOSURE 3

ENCLOSURE 4

DRAFT CONGRESSIONAL LETTER

Dear Mr. Chairman:

Enclosed for the information of the Subcommittee are copies of Nuclear Regulatory Commission effective amendments to its regulations in 10 CFR Part 20 regarding the disposal of certain radioactive waste, mainly biomedical. Under these amendments, licensees will be permitted greater leeway in disposing of liquid scintillation media and animal carcasses containing tracer levels of hydrogen-3 (tritium) or carbon-14. Licensees are now required to dispose of these items by sending them to a radioactive waste burial ground or by obtaining special authorization from NRC for incineration or onsite burial.

The purpose of these amendments is to permit the licensee to dispose of these materials without regard to their radioactivity. These proposed amendments will also raise the limit for disposal of hydrogen-3 and carbon-14 by release to the sanitary sewerage system.

The final rule will be published in the Federal Register to be effective on publication. Enclosed also are copies of a public announcement to be released by the Commission in this matter in the next few days.

Sincerely,

John G. Davis, Director
Office of Nuclear Material Safety
and Safeguards

Enclosures:
1. Final Rule
2. Public Announcement

ENCLOSURE 4

ENCLOSURE 5

VALUE/IMPACT STATEMENT

OF AMENDMENTS TO 10 CFR 20

FOR DISPOSAL OF BIOMEDICAL WASTES

I. The Final Rule

A. Description - The principal current method for disposal of biomedical and aqueous waste containing tracer quantities of hydrogen-3 and carbon-14 under NRC regulations is to ship them to commercial radioactive waste disposal grounds. The amendments to 10 CFR 20 will allow licensees to dispose of these wastes without regard to their radioactivity. However, they will be subject to other federal, state and local regulations governing any other toxic property of the materials. Thus the amendments will allow licensees to dispose of certain biomedical and aqueous wastes using commercial or municipal refuse collection services, incineration, landfill, or other means, to the extent permitted by applicable, non-radioactive waste disposal regulations.

B. Need for the Rule - Byproduct material licensees are required under 10 CFR 30.41 to transfer licensed material only to persons licensed to receive byproduct material. About 51% of this waste is comprised of liquid scintillation vials, animal carcasses and aqueous fluids containing tracer quantities of hydrogen-3 or carbon-14. Present disposal in commercial radioactive waste disposal grounds necessitates the transportation of these wastes, generally over great distances, and at great expense to the licensees. The transportation of these materials poses a difficult materials

ENCLOSURE 5

handling problem because the scintillation medium is both flammable and toxic, and the decaying carcasses, in addition to being unsanitary, generate methane gas which can explode or otherwise rupture waste containers. Moreover, these wastes consume scarce waste disposal grounds capacity, which could otherwise be used for radioactive wastes that need to be buried. Finally, should the waste sites be closed for any reason, there could be a prompt and serious interruption of biomedical research activities throughout the nation.

10 CFR 20 should be amended to eliminate the problems involved in the transport or storage of these wastes and the unnecessary consumption of scarce waste disposal grounds capacity.

C. Value/Impact of the Action

1. NRC Operations - The amendments to 10 CFR 20 will reduce the impact on NRC resource requirements. The licensing staff will not need to consider licensing amendments, such as incineration, for alternatives to commercial disposal of these materials. It will also reduce the number of waste packages that need to be inspected. The amendments will require no new reporting, new funding, nor time or personnel resources once the final rule is published.

2. Other Government Agencies - NRC Agreement States could make similar amendments to their regulations in order to extend the benefits to licensees in those states. The value to the Agreement States would be similar to that of the NRC.

3. Licensees - The primary value of the amendments will be to biomedical research institutions, and to a lesser extent, nuclear medicine laboratories. Other types of laboratories might also receive some benefits. The value results from a reduction of cost for disposal of scintillation vials, animal carcasses, and certain aqueous fluids. Current costs for licensees that generate waste for packing materials, transportation and disposal of these wastes as now required are estimated below (does not include cost of licensee labor or overhead):

   a. For Liquid Scintillation Counting Waste (LSCW) (see Attachment 1 for documentation of biomedical waste statistics):

      Total low-level waste (LLW) shipped to a burial site = 3×10^6 ft^3/year

      Approximately 30% of LLW is so-called institutional waste:

      3×10^6 ft^3/year x 0.3 = 9×10^5 ft^3/year

      About 43% of institutional waste is due to disposal of liquid scintillation vials or fluids:

      9×10^5 ft^3/yr x .43 $\approx$ 3.9×10^5 ft^3/year

      A 55 gallon drum will hold about 7.35 ft^3; thus:

      3.9×10^5 ft^3/year $\div$ 7.35 ft^3/drum $\approx$ 53,000 drums/year

We estimate the average cost of packaging materials, transportation, and burial of a drum of liquid scintillation waste to be at least $250.

Therefore, the estimated total cost for annual shipments of liquid scintillation waste to disposal grounds is:

53,000 drums/year x $250/drum = $13,250,000.

b. For Animal Carcasses - About 9% of institutional waste is comprised of animal carcasses, tissues, and other biological matter associated with biomedical research. From the above:

9×10^5 ft^3/year x 0.09 = 81,000 ft^3/year

or

8.1×10^4 ft^3/year ÷ 7.35 ft^3/drum = 11,020 drums of biological waste.

We estimate the average cost of packaging materials, transportation and burial of a drum of biological waste to be at least $300.

Thus, the estimated total cost for annual shipments of biological waste to disposal grounds is:

11,020 drums/year x $300/drum = $3,306,000.

c. For aqueous waste - No data are available to estimate the number of drums of absorbed or solidified aqueous waste shipped to disposal grounds. It is believed, however, that in revising the 1 curie limit contained in 10 CFR 20.303 to 5 curies and 1 curie for hydrogen-3 and carbon-14, respectively, some benefit will accrue to institutions engaged in biomedical research. Industrial facilities will be little affected by the proposed amendments to increase the sanitary sewerage limits for hydrogen-3 and carbon-14. The scale of research using hydrogen-3 and carbon-14 tracers in industrial facilities is generally small and is unlikely to lead to many industrial licensees' research activities taking advantage of the rule change. There are, however, some industrial licensees (e.g., manufacturers of labeled compounds, luminous source manufacturers, etc.) who might benefit from the rule change. However, they are relatively small in number and, therefore, would not contribute significantly to the total environmental release nor realize substantial cost savings.

To summarize the savings to licensees that generate waste, the proposed amendments will save approximately $16,000,000 in waste disposal costs; most of these savings will be realized in biomedical research. New costs will be incurred, however, in the disposal of these wastes through conventional means. Since conventional disposal is much cheaper than transport and burial at radioactive waste disposal grounds, it is estimated that the net savings will be about $13,000,000.

The amendments will result in a loss of revenue due to the elimination of most shipments from biomedical facilities to licensees that operate waste disposal facilities. These shipments currently account for 10% of annually buried waste and therefore are not an economic necessity. The amendment will prolong site use at a time when disposal capacity is in short supply.

4. Public/Environmental - The decrease in costs to biomedical facilities for waste disposal will allow these resources to be used in productive areas of biomedical investigation for the public benefit. There should be no increased costs to the public resulting from these amendments. The public will also benefit through the continued operation of biomedical facilities in the event of an embargo at disposal grounds and from the ability of the grounds to accept additional volume of other types of radioactive waste.

   The effects of the amendments on the environment were analyzed. Estimated exposures are as follows:

   a. With respect to alternative disposal methods for the liquid scintillation medium and animal carcasses, we have concluded that incineration would provide the greatest radiation impact on the environment.

To calculate the dose to the maximum exposed individual, an individual living near a very large biomedical research facility was considered (see Attachment 2). It was assumed the facility generated about 275 mCi of tritium and 75 mCi of carbon-14 in liquid scintillation and carcass wastes combined each year, and that all these wastes were incinerated. For the dose due to inhalation, it was assumed the individual remained at a distance of 40 meters from the incinerator stack for the entire year. Using inhalation rates, dose conversion factors and other data contained in Regulatory Guide 1.109, "Calculation of Annual Doses to Man From Routine Releases of Reactor Effluents for the Purpose of Evaluating Compliance with 10 CFR Part 50, Appendix I," the doses to the total body (for hydrogen-3) and bone (for carbon-14) were calculated. The results estimate the dose from the hydrogen-3 to be 0.01 mrem/year and 0.04 mrem/year from carbon-14.

For the dose from ingestion, it was assumed the individual subsisted completely on food grown or water located at a distance of 40 meters from the incinerator stack. Using ingestion parameters from a model developed by Oak Ridge National Laboratory, the doses to the whole body (critical organ for hydrogen-3) and bone marrow (critical organ for carbon-14) were calculated, yielding a dose of about 0.03 mrem/year from hydrogen-3 and 5.3 mrem/year from carbon-14.

Thus, the maximum individual exposure calculated to result from this disposal scenario is on the order of 5 mrem per year, or about 1/20 of the dose considered to be natural background radiation. Furthermore, the assumptions used greatly exaggerate any actual dose to a member of the public, which would likely be much less than 1 mrem/year, considerably less than EPA's 4 mrem drinking water standard for hydrogen-3.

Disposal of these wastes via municipal solid waste was also considered. Appendix D of an NRC sponsored Study of Consumer Products Containing Radioactive Material developed a calculational technique for examining the impacts of disposal of consumer products into municipal refuse. Consideration of this analysis with respect to municipal refuse disposal of liquid scintillation media or animal carcasses leads to the conclusion that the dose from this disposal alternative would be minor relative to that from incineration.

b. With respect to increasing the annual sewerage release limit for hydrogen-3 and carbon-14 to 5 and 1 curies respectively, the maximum ingestion dose was calculated for an individual subsisting on the nearest potable water supply downstream from the sewerage treatment plant. It was assumed a very large user of hydrogen-3 and carbon-14 was located immediately upstream from the treatment plant, and that the five curies of hydrogen-3

and one curie of carbon-14 were discharged at a constant rate over a one-year period. Using the dose conversion factor and other data from Regulatory Guide 1.109, the doses to the whole body (critical organ for hydrogen-3) and bone (critical organ for carbon-14) were calculated. Assuming the facility was located in a metropolitan area, the dose from hydrogen-3 contributed by the rule change would be about 0.06 mrem/year and 0.3 mrem/year for carbon-14. The actual dose to a member of the public would be much less than 1 mrem, again less than EPA's 4 mrem standard for drinking water for hydrogen-3. Even if multiple releases occurred in the same sewerage system, it can be seen by inspection that the resulting dose would be less than a couple of millirem. Since the amount of hydrogen-3 and carbon-14 released to the environment due to the proposed amendments is orders of magnitude less than natural levels, and since the probable dose to exposed members of the public is less than 1 mrem per year, it is concluded that the proposed amendments have no significant impact on the environment.

This rule will not result in a change in the total quantity of hydrogen-3 and carbon-14 as waste. It is estimated that under the new rule the resulting health effects will be much less than one per year even including the world population integrated over all time.

D. Decision on the Rule Action - The proposed amendments should be published in the Federal Register as a final rule.

II. Technical Approach

A. Technical Alternatives

Alternative 1: Rely on conventional waste disposal methods for scintillation vials and animal carcasses less than 0.05 μCi/gm in hydrogen-3 or carbon-14 concentration, subject to regulations regarding disposal of non-radioactive waste.

Provides immediate elimination of long-distance transportation hazards with no significant increase in risks to the public or licensees. Alternative waste management systems (e.g., collection services or sewerage system) are already established. Greatly reduced cost to licensees and to a lesser extent to NRC will result from this alternative.

Alternative 2: Establish new disposal sites that would accept biomedical waste.

There is some difficulty in keeping the three existing disposal grounds open due to a variety of problems, including public concern. It is unlikely that any new sites will be operational soon. If new sites are established, transportation costs might be reduced; however, the same problems would exist except there would be some increase in disposal capacity.

Alternative 3: As an interim solution, require licensees to store biomedical waste on site.

This alternative would require a change in the license of a great many affected licensees, resulting in considerable expenditure of time and personnel resources for both licensees and the NRC. This alternative will also expose licensees to hazards similar to those involved in the transport of the wastes, i.e., fire and toxic hazard of scintillation vials, and sanitation and explosion hazard from decaying carcasses. This alternative does not solve the problem because the long half-lives of hydrogen-3 (12 years) and carbon-14 (5,730 years) require the wastes to be disposed of eventually.

Alternative 4: Cease biomedical research and other activities involving uses of hydrogen-3 and carbon-14.

This alternative would be unacceptable to the public, who derive great benefit from biomedical research and other activities involving hydrogen-3 and carbon-14.

Alternative 5: Wait for exemptions as part of the general rule for low-level waste (10 CFR Part 61).

Relief is needed now. The rule would not be an effective regulation until 1982 at the earliest.

B. Decision on Technical Approach - The proposed amendments should be published in the Federal Register as a final rule, relying on the technical approach described in Alternative 1.

III. Procedural Approach

A. Procedural Alternatives

Alternative 1: Amend 10 CFR 20 through (1) addition of a new Part 20.306 to allow disposal of scintillation vial medium and animal carcasses containing less than 0.05 μCi/gm of hydrogen-3 or carbon-14 subject to other applicable disposal regulations; and (2) the modification of 10 CFR 20.303 to allow disposal of aqueous waste containing hydrogen-3 or carbon-14 to a maximum of 5 curies per year for hydrogen-3 and 1 curie per year for carbon-14.

This alternative provides immediate relief from the current storage and transportation problems associated with biomedical waste. It assures continued operation of facilities using hydrogen-3 and carbon-14 in the event of an embargo at disposal grounds. This alternative can also be implemented at little or no cost to either NRC, its licensees, or the public. Environmental impacts from a radiation standpoint will be negligible.

Alternative 2: Allow licensees to apply for license modifications (e.g., incineration) permitting the disposal of biomedical and aqueous wastes. This alternative would require months, even years, before all the license modifications could be reviewed and approved. Therefore, it would not eliminate the storage and transport hazard of biomedical waste, nor does it assure all facilities will remain operational in the event of disposal ground embargoes. This alternative would require expenditure of licensee resources to prepare the license modifications and NRC resources to review the modifications. For many licensees there is little if any option under the present regulations other than sending the waste to burial grounds. For example, many licensees located in metropolitan areas have state or local laws prohibiting incineration, and they are not located upon sites in which they can bury their own wastes.

B. Decision on Procedural Approach - The procedural approach described in Alternative 1 should be used in the final rule.

IV. Statutory Considerations

A. NRC Authority - The amendments fall under the authority and safety requirements of the Atomic Energy Act of 1954, as amended.

B. Need for NEPA Statement - The proposed action is non-substantive and insignificant from a standpoint of environmental impact and therefore does not require either an environmental impact statement or a negative declaration.

V. Relationship to Other Existing or Proposed Regulations on Policies - No conflicts or overlaps with requirements promulgated by other agencies are foreseen. The amendments are consistent and in accord with the Commission's regulations and policies.

VI. Summary and Conclusions - The proposed amendments to 10 CFR 20 on biomedical and aqueous waste disposal should be published in the Federal Register as a final rule.

BIOMEDICAL WASTE STATISTICS

The total activities and volumes of biomedical waste here were derived from average concentrations reported in various laboratories, from biomedical supply houses, NUREG/CR-1137, and data files of NRC's Division of Waste Management. An early NUS Corporation report entitled "Preliminary State-By-State Assessment of Low-Level Radioactive Wastes Shipped to Commercial Burial Grounds" reported much higher total activities than those estimated here. The data in this report are now believed, however, to overestimate the quantities of biomedical wastes, and the report is being revised by the authors to reflect a reassessment of biomedical waste shipments.

The following sections document or show the derivation of biomedical waste statistics used in this paper. The sections included are:

I Summary of Annual U. S. Low Level Radioactive Waste Volume

II Estimated Total Volume of Liquid Scintillation Counting (LSC) Media Waste

III Reported Radioactivity Concentrations and Estimated Total Activities for Liquid Scintillation Counting Media

IV Estimated Annual Activity of Hydrogen-3 and Carbon-14 Contained in Biological Waste

V Estimated Total Radioactivity of Hydrogen-3 and Carbon-14 in the Liquid Scintillation Counting (LSC) and Biological Wastes Generated Annually in the United States

I SUMMARY OF ANNUAL U.S. LOW LEVEL RADIOACTIVE WASTE VOLUME

	Annual Volume		Per Cent of	
	55 gal. drums*	Cubic Feet	Total Low Level Waste	Reference
Total Low Level Waste	408,200	3,000,000	100.0	1
Institutional Waste**	122,400	900,000	30.0	1
Liquid Scintillation Counting Waste	53,060	390,000	12.9	2
Biological Waste***	11,020	81,000	2.7	2

*Volume of a 55-gallon drum = 7.35 ft^3

**Institutional waste as used here includes low level radioactive waste not generated by industrial facilities or nuclear power plants or the supporting nuclear fuel cycle facilities.

***Biological waste as used here includes animal carcasses and tissues from biomedical research facilities.

References:

1. NRC Division of Waste Management: "General Description of Low Level Waste Generated for Commercial Disposal in the United States," October 1979.
2. NUREG/CR-1137, Institutional Radioactive Wastes, published October 1979, Table 3.13, p. 44, discussion p.67.

II ESTIMATED TOTAL VOLUME OF LIQUID SCINTILLATION COUNTING (LSC) MEDIA WASTE

The exact volume of LSC media waste is unknown, but the range of the volume can be estimated.

The lower range value is based on the annual production of liquid scintillation vials and an estimate of the number of liquid scintillation counters in the United States. Mr. C. Killian of New England Nuclear Corporation, the largest producer of scintillation vials in this country, has estimated that in total 7,000 vials are produced for each of 12,000 counters each year. Hence:

$$7{,}000 \text{ vials/counter/yr} \times 12{,}000 \text{ counters} = 84 \times 10^6 \text{ vials/yr}$$

Assuming each vial contains 10 ml:

$$84 \times 10^6 \text{ vials/yr} \times 10 \text{ ml/vial} = 840{,}000 \text{ liters/yr or}$$

221,800 gallons of liquid scintillation media per year.

For the upper range value, the total number of LSC vials disposed of annually in the U.S. is calculated from the estimated number of LSC waste drums and the maximum number of vials disposed of per drum. Using the previous estimate of 53,060 drums of LSC waste and assuming 3,000 vials per drum (NUREG-1137, p. 67 suggests 2200-3000 vials/drum), we have:

$$53{,}060 \text{ drums/year} \times 3{,}000 \text{ vials/drum} = 159 \times 10^6 \text{ vials/year}$$

Again, at 10 ml/vial:

$$159 \times 10^6 \text{ vials/yr} \times 10 \text{ ml/vial} = 1{,}590{,}000 \text{ liters/yr or}$$

419,800 gallons of liquid scintillation media per year.

The volume of liquid scintillation media is thus estimated to be between 221,800 and 419,800 gallons per year.

III REPORTED RADIOACTIVITY CONCENTRATIONS AND ESTIMATED TOTAL ACTIVITIES FOR LIQUID SCINTILLATION COUNTING MEDIA

	Concentration Ci/vial	Reference	Total Activity in Curies per Year Assuming: 84×10 vials/yr	159×10 vials/yr
Hydrogen-3				
	0.004	1	0.3 Ci/yr	0.6 Ci/yr
	0.070	2	5.9	11.1
	0.019	3	1.6	3.0
	0.100	4	8.4	15.9
	0.280	5	23.5	44.5
	0.001	6	0.8	1.6
Carbon-14				
	0.00015	1	0.13 Ci/yr	0.2 Ci/yr
	0.00021	2	0.18	0.3
	0.00019	3	0.16	0.3
	0.00080	5	0.67	1.3
	0.00010	6	0.08	0.159
	0.00017	7	0.14	0.3

References:

1. Personal communication with Dr. Robert Hamilton, Chief of Radiation, Physics Dept. of V.A. Medical Center, Bronx, New York, and Professor of Nuclear Medicine of Albert Einstein College of Medicine. Also includes data from Columbia Presbyterian Medical Center, New York. August 1980.
2. NUREG/CR-1137, Institutional Radioactive Wastes, published October 1979, pp. 58 and 60.
3. Personal communication with Roger Broseus, National Institutes of Health, August 1980. Reported concentrations are an average.
4. Captain W. H. Briner, NRC consultant. Concentration given is an upper limit.
5. Personal communication with Leland Cooley, Radiation Safety Office, University of Maryland, August 1980. This is a high concentration estimated average from reviewing data from 100 LSC drums.
6. Personal communication with C. Killian, Environmental Control Director, New England Nuclear, August 1980.
7. NUREG/CR-0028, Institutional Radioactive Wastes, published March 1978, p. 49.

IV ESTIMATED ANNUAL ACTIVITY OF HYDROGEN-3 AND CARBON-14 CONTAINED IN BIOLOGICAL WASTE

NRC's Division of Waste Management recently sponsored a study of waste categories which the prime contractor, Dames & Moore, subcontracted to Leland Cooley at the University of Maryland.* Based on a survey of large waste generating institutions believed to account for approximately 21% of the biological waste in the United States, the study estimated the annual activity contained in animal carcasses, tissues, excreta, and bedding, combined, to be 3.23 curies of hydrogen-3 and 1.26 curies of carbon-14.

The 21% share of total U.S. biological waste estimated for these large institutions may underestimate their actual contribution by 10% or more. If the 21% figure is assumed, however, the annual U.S. biological waste would be calculated to contain 15.4 Ci of hydrogen-3 and 6.0 Ci of carbon-14.

*Unpublished data

V ESTIMATED TOTAL RADIOACTIVITY OF HYDROGEN-3 AND CARBON-14 IN THE LIQUID SCINTILLATION COUNTING (LSC) AND BIOLOGICAL WASTES GENERATED ANNUALLY IN THE UNITED STATES

	Waste	Total Activity in Ci/year Assuming Average or Maximum Concentrations	
Hydrogen-3		Range or Average	Maximum
	LSC	11.0 - 16.0	44.5
	Biological	15.4 15.4	15.4
		26.4 - 31.4	59.9
		28.0	60.0
Carbon-14			
	LSC	0.3	1.3
	Biological	6.0	6.0
		6.3	7.3

Disposal of Liquid Scintillation Media and Animal Carcasses Containing Tracer Levels of H-3 or C-14 Without Regard to Their Radioactivity:

Estimates of Maximum Potential Radiation Dose to an Individual and Total Collective Dose

The radiation dose commitment to an individual due to disposal of liquid scintillation counting wastes and animal carcasses containing H-3 and C-14 is calculated in this report. Both inhalation and ingestion pathways are considered in the calculations. Since H-3 and C-14 are low energy beta emitters, the external exposure from these two sources will not be considered. The dose commitment is calculated according to the following basic equation.

$$D = C \times U \times DCF$$

Where D is the dose commitment to a given organ of an individual, in mrem/yr; C is the concentration of a nuclide in the media, in pCi/liter, U is the usage factor unit in liter/yr, and DCF is the dose conversion factor in units of

$$\frac{\text{mrem}}{\text{pCi}} \quad \text{or} \quad \frac{\text{mrem}}{\text{yr}} \quad \text{per} \quad \frac{\text{Ci}}{\text{m}^3}$$

(I) Inhalation Mode

Dose commitment to an individual is calculated based on the assumption that the individual inhaled contaminated effluents produced by combustion of animal carcasses and liquid scintillation counting wastes containing H-3 and C-14. The calculation is also based on the following assumptions:

(1) H-3 and C-14 enter the human body by inhalation in the form of HTO and CO_2 respectively.

(2) Source terms: total activity* to be burned over a year for H-3 and C-14 is 0.275 Ci and 0.075 Ci respectively.

* Represents the annual activities in the liquid scintillation wastes and animal carcasses generated in large research and medical institutions in this country as determined in an NRC in-house survey.

(3) The nearest resident is located about 10-40 meters from the incinerator. The air concentration once exiting the incinerator will be reduced by an atmospheric dilution factor of 10^{-3} sec/m^3 when it reaches the nearest resident.

(4) The incinerator is operated 2000 hours per year.

Dose From Inhalation

$$D = C \times U \times DCF$$

Where D = Dose commitment due to inhalation by an individual remaining at a distance of 40 meters downwind from the incinerator for the entire year;

C = Concentration of radioactive effluents at 10-40 meters from the incinerator, and is calculated as follows:

$$C = \frac{\text{Activity (Ci)}}{\text{incinerator operation time (hrs)}} \times X/Q \ \frac{\text{sec}}{m^3} \times \frac{\text{hrs}}{3600 \text{ sec}}$$

For H-3:

$$= \frac{0.275 \text{ Ci}}{2000 \text{ hrs}} \times 10^{-3} \ \frac{\text{sec}}{m^3} \times \frac{\text{hrs}}{3600 \text{ sec}}$$

$$= 3.8 \times 10^{-11} \ \frac{\text{Ci}}{m^3} = 3.8 \times 10^{1} \ \frac{\text{pCi}}{m^3}$$

For C-14:

$$= \frac{0.075\ Ci}{2000\ hrs} \times 10^{-3}\ \frac{sec}{m^3} \times \frac{hrs}{3600\ sec}$$

$$= 1.0 \times 10^{-11}\ Ci/m^3 = 1.04 \times 10^{1}\ pCi/m^3$$

Breathing rate, U:

$$U = 8000\ m^3/yr \times \frac{yr}{8760\ hr} \times \frac{2000\ hr}{yr} = 1.83 \times 10^{3}\ m^3/yr$$

DCF: Dose conversion factors for inhalation dose were obtained from Regulatory Guide 1.109.

DCF for H-3 (total body as critical organ) is $1.58 \times 10^{-7}\ \frac{mrem}{pCi}$

DCF for C-14 (bone as critical organ) is $2.3 \times 10^{-6}\ \frac{mrem}{pCi}$

Dose due to inhalation of H-3

$$D_{H-3} = 3.8 \times 10^{1}\ \frac{pCi}{m^3} \times 1.83 \times 10^{3}\ \frac{m^3}{yr} \times 1.58 \times 10^{-7}\ \frac{mrem}{pCi}$$

$$= 0.01\ mrem/yr\ \text{(total body)}$$

Dose due to inhalation of C-14:

$$D_{C-14} = 1.04 \times 10\ \frac{pCi}{m^3} \times 1.83 \times 10^{3}\ \frac{m^3}{yr} \times 2.3 \times 10^{-6}\ \frac{mrem}{pCi}$$

$$= 0.04\ mrem/yr\ \text{(bone)}$$

(I') Ingestion Mode

The estimated dose due to dietary and drinking water intake of H-3 and C-14 from incineration of biomedical wastes is also calculated under assumptions 2 and 3 listed for the inhalation mode. In addition, it is assumed the food and drinking water are in equilibrium with the

specific activity of H-3 in the atmosphere, and the specific activity of C-14 in human tissue is equal to the average steady-state value in the atmosphere. The methodology of the calculation is presented fully in ORNL-4992, "A Methodology for Calculating Radiation Dose from Radioactivity Release to the Environment."

A. Dose from ingestion:

$$D = C \times DCF$$

Where D = Dose in mrem/yr due to dietary and drinking water intake;

C = Annual average concentration of radioactivity at 10-40 meters from the incinerator resulting from the incineration of 0.275 Ci H-3 and 0.075 Ci of C-14 annually.

For H-3:

$$C = \frac{0.275 \text{ Ci}}{\text{yr}} \times 10^{-3} \frac{\text{sec}}{\text{m}^3} \times \frac{\text{hrs}}{3600 \text{ sec}}$$

$$= \frac{0.275 \text{ Ci}}{8760 \text{ hr/yr}} \times 10^{-3} \frac{\text{sec}}{\text{m}^3} \times \frac{\text{hrs}}{3600 \text{ sec}}$$

$$= 8.7 \times 10^{-12} \text{ Ci/m}^3$$

For C-14:

$$C = \frac{0.075 \text{ Ci}}{8760 \text{ hr/yr}} \times 10^{-3} \frac{\text{sec}}{\text{m}^3} \times \frac{\text{hrs}}{3600 \text{ sec}}$$

$$= 2.4 \times 10^{-12} \text{ Ci/m}^3$$

DCF = Dose conversion factor in mrem/yr/Ci/m^3, annual dose rate per unit air concentration of H-3 or C-14 radioactivity at the point of interest (data taken from ORNL-4992):

For H-3, with total body as critical organ:

$$DCF = 3.68 \times 10^{9} \text{ mrem/yr/Ci/m}^3$$

For C-14, with bone marrow as critical organ:

$$DCF = 2.22 \times 10^{12} \text{ mrem/yr/Ci/m}^3$$

Dose due to ingestion of H-3:

$$D = 3.68 \times 10^{9} \text{ mrem/yr/Ci/m}^3 \times 8.7 \times 10^{-12} \text{ Ci/m}^3$$

$$= 0.03 \text{ mrem/yr to total body}$$

Dose due to ingestion of C-14:

$$D = 2.22 \times 10^{12} \text{ mrem/yr/Ci/m}^3 \times 2.4 \times 10^{-12} \text{ Ci/m}^3$$

$$= 5.33 \text{ mrem/yr to bone marrow}$$

B. Dose due to drinking water contaminated from sewer releases of H-3 and C-14.

The dose is calculated to an individual who subsists on the potable water supply from the sewage treatment plant. It is further assumed that a very large user of tritium and carbon-14, located in a metropolitan area and upstream from the treatment plant, discharged 5 curies of H-3 and 1 curie of C-14 into the sewer in a single day. The doses to the critical organ of an individual were calculated by using dose conversion factors given in NRC Regulatory Guide 1.109.

Dose from Ingestion

$$D = C \times U \times DCF$$

D = Dose in mrem/yr due to ingestion of contaminated water

C = Potable water concentration of H-3 and C-14. It is assumed that the discharged 5 Ci of H-3 and 1 Ci of C-14 was diluted by a volume of 5×10^6 gallons water at releasing point of the water treatment plant. 5×10^6 gallons of water represents the total water that is being handled each day by a large city's water treatment facility.

For H-3:

$$C = \frac{5 \text{ Ci/yr} \times 10^{12} \text{ pCi/Ci}}{5 \times 10^{6} \text{ gal/day} \times 3.785 \text{ l/gal} \times 365 \text{ days/yr}} = 7.2 \times 10^{2} \frac{\text{pCi}}{\text{liter}}$$

For C-14:

$$C = \frac{1 \text{ Ci/yr} \times 10^{12} \text{ pCi/Ci}}{5 \times 10^{6} \text{ gal/day} \times 3.785 \text{ l/gal} \times 365 \text{ days/yr}} = 1.4 \times 10^{2} \frac{\text{pCi}}{\text{liter}}$$

U = Water consumption rate per year = 730 liter/yr max.

DCF = Dose conversion factors for ingestion

For H-3: $1.05 \times 10^{-7} \frac{\text{mrem}}{\text{pCi}}$ (Total body as critical organ)

For C-14: $2.8 \times 10^{-6} \frac{\text{mrem}}{\text{pCi}}$ (Bone as critical organ)

Dose due to ingestion of H-3:

$$D = 7.2 \times 10^{2} \frac{\text{pCi}}{\text{liter}} \times 730 \text{ liter/yr} \times 1.05 \times 10^{-7} \frac{\text{mrem}}{\text{pCi}}$$

$$= 5.52 \times 10^{-2} \text{ mrem/yr}$$

$$= 0.06 \text{ mrem/yr (Total body)}$$

Dose due to ingestion of C-14:

$$D = 1.4 \times 10^{2} \frac{pCi}{liter} \times 730 \frac{liter}{yr} \times 2.8 \times 10^{-6} \frac{mrem}{pCi}$$

$$= 0.3 \text{ mrem/yr (Bone)}$$

Collective Dose Assessment

For the scintillation media and animal carcass amendment:

The collective doses resulting from the rule change may be readily calculated by assuming that all the hydrogen-3 and carbon-14 used in scintillation media and animal carcasses in a year is released to the environment through incineration.

The population of the United States is employed in calculating the collective dose. Employing the calculational approach used in the Final Generic Environmental Statement on the Use of Recycle Plutonium in Mixed Oxide Fuel in Light Water Cooled Reactors (GESMO), it is estimated that 100 curies of hydrogen-3 delivers 1 person-rem to the U.S. population. Since 28 curies of hydrogen-3 could be released per year as a result of the rule, this would yield 0.28 person-rem in total. The National Academy of Sciences BEIR-III report estimates 1 health effect per 10,000 person-rem. Hence we estimate 0.00003 health effects per year from the release of hydrogen-3.

For carbon-14, the model described in the report entitled "A Diffusion-Type Model of the Global Carbon Cycle for the Estimation of Dose to the World Population from Releases of Carbon-14 to the Atmosphere," ORNL-5267, was used. This report indicates a collective dose commitment of 620 person-rem per curie of carbon-14, or 3,720 person-rem in total for the 6 curies released each year via the rule. Again, using the 1 health effect per 10,000 person-rem from the BEIR-III report, we estimate a total of 0.37 health effects to the world population. Hence, employing assumptions which overestimate the likely exposures, we conclude the rule change would result in less than one health effect per year.

For the sewer release amendment:
To calculate the collective dose from this change, we assume drinking water is the primary pathway and that all the radioactivity released will be consumed by the U.S. population.

Assuming water contains about 300 pCi/ℓ of hydrogen-3 from natural sources, and that the maximum personal consumption of water is 730 ℓ/yr, we have:

$$300\ \text{pCi}/\ell \times 730\ \ell/\text{person/yr} \times 1 \times 10^{-7}\ \text{mrem/pCi} \times 225 \times 10^{6}\ \text{persons in U.S.}$$

= 5000 person-rem/yr to US population from naturally occurring hydrogen-3 in drinking water.

Multiplying the collective dose from naturally occurring hydrogen-3 in drinking water by the ratio of the quantity released by the rule and the quantity naturally in the environment yields an approximation of the collective dose due to the rule change. If we assume 25 facilities all release 5 curies, we have 125 Ci total or

$$\frac{125 \text{ Ci (released)}}{28 \times 10^6 \text{ Ci (environmental inventory)}} \times 5000 \text{ person-rem} = 0.02 \text{ person-rem}$$

At 10,000 person-rem/health effect, this results in very much less than 1 health effect per year.

Carbon-14 is known to contribute about 1% of the natural background dose to the U.S. population. If the average background dose per person is 0.1 rem, the natural background dose is about 22.5×10^6 person-rem with 2.25×10^5 person-rem due to carbon-14.

We again determine the fraction of this collective dose, received primarily through ingestion of naturally occurring carbon-14, that would result from the rule. Thus, if 25 facilities all released 1 curie of carbon-14, a total of 25 curies would be released. Since we estimate that 2.25×10^5 person-rem is received by the U.S. population from the 280 million curies in the environment, we can approximate that an additional 25 curies would yield an additional

$$\frac{25 \text{ Ci (released)}}{280 \times 10^6 \text{ Ci (environmental inventory)}} \times 2.25 \times 10^5 \text{ person-rem} = 0.02 \text{ person-rem}$$

Again, at 10,000 person-rem/health effect, this would yield very much less than 1 health effect per year.

Even if our results were in error by a couple orders of magnitude, the conclusion would remain the same: the collective doses and health effects resulting from the rule are estimated to be so small that they are negligible.

ENCLOSURE 6

ANALYSIS OF COMMENTS

The NRC received 321 comments on the proposed rule. Most comments originated from academic institutions and medical facilities, with the remainder sent from industry, government agencies, professional groups, private citizens, and special interest groups.

Favorable Comments

Of the 321 comments, 271 supported the proposed rule, with many requesting that the rule be expanded to include other low-level wastes. While the staff intends to explore regulatory options for other waste streams, this will be accomplished through separate actions.

Most of the supporting comments indicated that the rule change would: safeguard the health and safety of the public; reduce the potential for interruption of biomedical research due to closure of burial grounds; reduce the unnecessary and costly burden of current disposal practices; and conserve radioactive waste burial grounds space.

Among the many organizations lending their support to the rule was the American Medical Association, which stated:

> "We applaud the NRC's proposal, which is consistent with the protection of the public health, safety and welfare, to reduce the volume of low-level radioactive waste to be buried and to thereby conserve critically necessary waste burial capacity."

Other professional groups and associations supporting the rule included the American College of Nuclear Physicians; the Society of Nuclear Medicine; the American Board of Nuclear Medicine; the American College of Radiology; the Association of Physicists in Medicine; the American Hospital Association; and the Association of American Medical Colleges and Universities, as well as many acclaimed medical research institutions across the country.

Many comments stressed the benefits of the amendment regarding scintillation media and animal carcass waste. Typical statements include the following:

> "The rule is a major step toward developing environmentally safe procedures to reduce low level waste volumes in the United States. NRC is to be commended for its recognition of the need for and its speed in developing the solution. All organizations that have studied low level waste problems recognize that much of the waste moving into the three disposal sites is of such low radioactivity content that it should be treated as nonradioactive in view of the high cost of disposing C-14 and H-3 and the large amount of disposal space being taken by this low hazard waste."

> "The rule will conserve burial space for more appropriate use, and will allow the disposal of media and carcasses in conformity with their major hazards rather than a minor consideration. As a teacher, public spirited citizen, environmentalist, conservationist, and taxpayer, I hope to hear in due course that this eminently sensible and cautious change has been approved."

> "I believe that a large amount of effort is expended in trying to meet previous regulations which actually is more damaging to the health of my laboratory personnel than would be the small amounts of radiation, i.e., the difficulties of lung and skin exposure to toluene-based fluids in the handling process (despite using hoods, wearing gloves, etc.) are a greater hazard than the small amounts of radiation."

Comments Identifying Problem Areas or Requesting Clarification

A number of comments expressed concern about possible impacts of the rule or otherwise requested clarification of the various aspects of the proposed amendments.

The Natural Resources Defense Council (NRDC) was concerned that NRC's case-by-case approach to raising de minimis (sic) levels would prevent consideration of cumulative health effects and physical impacts on sanitary disposal systems. NRDC also felt that similar rule changes taken collectively might warrant preparation of an Environmental Impact Statement (EIS) as required by the National Environmental Policy Act (NEPA). Other comments stated that disposal by release and dilution in the environment sets a dangerous precedent.

In identifying and proposing these amendments for biomedical waste, NRC is complying with the request of the Federal Radiation Policy Council to present "an interim plan for the identification and analysis of specific waste streams beginning with the C-14 and H-3 (tritium) medical waste streams for which early action is appropriate." Furthermore, the total quantities that would be released are less than .001% of the natural inventory of these radionuclides in the environment and would be released in any event under current regulations.

A number of comments questioned the derivation of the 0.05 microcuries per gram level for scintillation media and animal carcasses, and suggested changing this level to anywhere from 0.2 microcuries per gram to 0.02 microcuries per gram, or establishing different levels for each waste. The 0.05 microcuries per gram level was recomended to the Commission by its expert consultants as a level

which would encompass most biomedical research involving tracer use in animals. While the level might be slightly higher than that normally encountered in liquid scintillation work, it simplifies the administrative burden of the rule by eliminating exacting calculations and surveys that would be required if the level were set very close to working levels. Moreover, liquid scintillation counting equipment can be saturated if too much radioactivity is used, hence even if the level is above that required for average situations, this is not expected to change the quantity of radioactivity from that used currently.

Several comments requested clarification on the scope of the amendment concerning scintillation media and animal carcasses, i.e., whether the amendment includes the scintillation vials containing the media, and whether it includes tissues, organs, or fluids removed from the carcasses. With regard to the first matter, there appears to have been concern that if a licensee emptied the scintillation medium from a vial, the vial, containing a residue of the medium, could not be disposed of along with the medium itself. Scintillation vials themselves are not radioactive. Rather, it is the scintillation media remaining in the vials that contains the radioactivity. The rule covers that material. Therefore, it would be permissible to dispose of the used vials along with the media.

Researchers wanted to know whether the rule applied to an organ of a research animal in which the H-3 or C-14 might concentrate and exceed the 0.05 microcuries per gram limit specified in the rule and perhaps might be later removed from the carcass. Organs and tissues, whether removed from the carcass or not, containing either more or less than 0.05 microcuries per gram, could be disposed of under the rule providing this material does not exceed 0.05 microcuries per gram of hydrogen-3 or carbon-14 per gram of animal tissue averaged over the weight of the entire animal.

Some commenters were concerned about the possibility of no one's accepting the waste covered by the rule change. It was postulated, for example, that some Agreement States might consider these wastes radioactive, but they would no longer be accepted by radioactive waste handlers; or that radioactive waste disposal facilities would refuse to accept them and chemical waste facilities would also refuse because the wastes are known to contain radioactivity. However, the staff is not aware of any reason to expect the burial sites to refuse to accept these wastes as a consequence of the proposed rule. While there might be a possibility that some chemical waste sites would refuse to accept these wastes because of their radioactivity, it does not change the merit of the rule.

Regarding incineration of the scintillation media and animal carcasses, the proposed amendments would permit licensees to incinerate these wastes without obtaining permission from NRC via a license amendment. The dose assessment in the value/impact statement shows that the doses would be small using assumptions that are conservative.

Two comments expressed concern that the proposed amendment for scintillation media and animal carcasses does not specify a limit for the total amount released. This is correct; however, the total amount released will be equal to or less than the total amount produced, the latter quantity being used in the value/impact assessment of possible health effects. This quantity is sufficiently small that even with reasonable growth in the quantity produced for research purposes, the conclusions of the value/impact assessment would not be expected to change.

A few comments expressed the opinion that NRC is simply backing itself out of a difficult situation and transferring the problem rather than resolving it. The staff believes the proposed rule and its supporting analysis stands on its own merit.

One comment expressed concern that the amendments would delay resolution of the need for new low level waste sites. Another comment stated that disposal site capacity should be made available for the safe disposal of health related radioactive materials first, thus assuring adequate burial capacity for these wastes. Decisions about establishing new disposal facilities involve many complex public and technical issues. While reduction of demand for burial capacity due to the rule change and the need for burial capacity to assure uninterrupted biomedical research might be factors in weighing such decisions, it is unlikely to change the balance of need for new capacity. Again, the proposed rule stands on its own merit and is justified independent of the need for additional disposal capacity.

One comment proposed that by diluting with solvent, a licensee could dispose of an unlimited pool of hydrogen-3 or carbon-14. This is possible but very unlikely. At the current prices for these solvents, such an approach is not cost effective and is virtually cost prohibitive.

Comments Concerning Disposition of Wastes

Several comments were concerned about possible misinterpretation of the rule's provisions leading to improper disposal of scintillation media in the sanitary sewer system. Scintillation media are flammable and should not be poured down the drain.

Several other comments inquired about who would have regulatory responsibility for these wastes, especially how these materials would be handled under EPA regulations. It is anticipated that local, state and federal agencies' regulations applicable to the disposal of nonradioactive wastes in the region in which the licensee is located will apply.

To clarify these points, the staff has accepted the suggestion by EPA to include a statement in the rule regarding the licensees' responsibility for proper disposal of the waste:

> "Nothing in this section relieves the licensee from complying with other federal, state and local regulations governing any other toxic or hazardous property of these materials."

Another comment inquired about the buildup of these wastes in the environment (e.g., groundwater) over many years, and its final disposition. While it is correct that perhaps an additional 28 curies of hydrogen-3 and 6 curies of carbon-14 could be released each year, it should be noted that 1.1 million curies of hydrogen-3 and 30 thousand curies of carbon-14 are generated in the environment each year as a result of natural processes. The additional radioactivity released under the proposed rule would blend uniformly with that naturally produced and could not be detected once incorporated in the huge environmental inventory of these radionuclides (28 million curies of hydrogen-3 and 280 million curies of carbon-14).

Several of the opposing comments came from private citizens. Their most frequent comment was that they did not like the idea of radioactive materials being spread into the environment, and were concerned about the effect of these releases on their health. These comments did not contain new information which would change the value/impact assessment. The final value/impact assessment estimates possible doses and health effects. These are very small and sufficient to justify the rule change.

One comment stated that "NRC radiological assessments are off by factors of 100 to 1,000." No technical evidence is presented, however, that supports these claims with respect to the proposed rule. The staff has not located errors which would increase assessment of impacts.

One comment stated that animal carcasses would pose problems as great at hazardous waste facilities as at nuclear waste facilities. Under the proposed rule, there would be little need to send carcasses to a hazardous waste facility. It is more likely that they would be incinerated, buried on site or shipped to sanitary landfill, where they biodegrade naturally.

Comments Requesting General Changes in the Rule

Two comments suggested that liquid scintillation could be replaced by other measurement techniques, or smaller scintillation vials could be used reducing the volume of these wastes. No alternatives to liquid scintillation were proposed, however, and while smaller vials may have some merit, the design of these research tools has already been standardized. To change over at this point would be extremely costly and the net reduction of environmental impacts would be very small.

One comment suggested that effluent concentrations (maximum permissible concentration [MPC]) should be used instead of concentration in the waste prior to incineration. Staff calculations indicate that even if 10% of the total quantity of these biomedical wastes were incinerated at a single facility, the maximum individual dose would be less than a millirem, which indicates the average effluent concentration would be 500 times less than the MPC.

Comments Addressing Increases in Sewer Release Limits

EPA stated in its comments that they did not believe the information presented was sufficient to support the need to raise the limits of hydrogen-3 and carbon-14 which can be discharged to sanitary sewers. However, EPA also stated that impacts would be small.

The staff believes that the analysis of sewerage releases contained in the value/impact analysis is sufficient to justify the rule change. The resources required to be spent by the government and licensees to gather more detailed

information concerning needs are not justified in the light of the nature of the change. (The need for this change has been expressed by the American Association of Medical Colleges, and since the resulting doses would be so small, we believe the levels should be increased.)

A couple of comments suggested that the sewer release limit should be based on the capacity of the sewer system and that the preliminary value/impact statement did not address the case of multiple licensees using the same sewer system. This would result in a vast array of release limits which would be very difficult and costly to administer. The staff believes the benefits would be very minimal if they existed at all. Even in the unlikely event that more than one licensee discharged into the same system above the one curie limit, the final value/impact statement shows that the impacts would be very small.

Two comments stated that no dilution factors had been provided in the amendment to increase the limits for hydrogen-3 and carbon-14 disposal by discharge into the sanitary sewer system. The proposed amendments specify only the limit on the quantity of annual releases. The concentration limits are already specified in 10 CFR 20.

A group of sanitation workers expressed concern that they might face an increased occupational hazard from the radioactive wastes, which they believed might concentrate in certain system components. Hydrogen-3 and carbon-14 are not believed to concentrate in the environment, hence there is no reason to expect any significant depositions in system equipment. Furthermore, these

nuclides emit beta radiations, which would more than adequately be shielded by any piping, conduit, ground, etc.

Another comment warned that "excluding" hydrogen-3 and carbon-14 from the current 1 curie limit on sewer disposal would increase the amounts of other isotopes discarded into the sewer. While it is possible to discharge 1 curie of radionuclides other than hydrogen-3 and carbon-14 under present regulations, it is very unlikely that the rule change would make a substantive difference in the total amount of radionuclides released into the sanitary sewerage system. Except for biomedical licensees, few use hydrogen-3 or carbon-14 and would not be affected by the rule change. Biomedical researchers typically do not have large quantities of other radioisotopes to discard into the sewer.